Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0990742	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Doctors Med Care	1024 South Horner Boulevard, Sanford, NC	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of random patient test reports, and testing personnel (TP) interview 3 /21/2019, the laboratory failed to record the identity of the personnel who performed the complete blood cell (CBC) testing. The laboratory performs CBC testing on the Cell-Dyn Emerald analyzer. Test reports are printed directly from the analyzer, initialed by TP and then scanned into the patient's chart. Review of 7 random patient CBC test reports, patient identification numbers 31719, 27573, 20344, 8186, 31550, 32775, and 33059, revealed 3 of 7 test reports did not include the TP initials to indicate who performed the testing. During exit interview at approximately 1:30 p.m., TP #1 confirmed the 3 test reports did not include the TP initials.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by:

	Based on surveyor record review and testing personnel interview 3/21/19 the laboratory director failed to evaluate all unacceptable proficiency testing (PT) results and failed to ensure an approved, corrective action plan was implemented to address unacceptable PT results. See deficiency cited at D6019.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policy/procedure manual, review of 2017, 2018 and 2019 American Proficiency Institute (API) proficiency testing (PT) records, review of laboratory "API SIGN OFF SHEET" records and testing personnel (TP) interview 3/21 /19, the laboratory director failed to ensure that all unacceptable PT results were evaluated and failed to ensure an approved, corrective action plan was implemented to address unacceptable PT results. Review of laboratory policy/procedure manual failed to reveal an approved corrective action plan for the laboratory to follow when unacceptable PT results were received. Review of 2017 and 2018 API Hematology /Coagulation PT records revealed the following events had unacceptable PT results and there was no documentation that the unacceptable results were reviewed and/or no corrective actions were implemented to evaluate the probable causes for the unacceptable PT results. 1. API 2017 1st event, unacceptable results for sample HEM-02, Lymphocytes and Monocytes. No review or corrective action documented. 2. API 2017 2nd event, unacceptable results for sample HEM-06, Lymphocytes and Monocytes and sample HEM-08, Monocytes. The performance review is signed by the laboratory director and the corrective action taken states, "Continue monthly maintenance. Mix samples correctly. Run daily QC." The corrective action documented fails to evaluate the probable cause of the unacceptable results. 3. API 2017 3rd event, unacceptable results for sample HEM-15, Hemoglobin. No review or corrective action documented. 4. API 2018 1st event, unacceptable results for samples HEM-01, Lymphocytes and Monocytes; HEM- 02, Hematocrit, "MCV", Monocytes, Platelet Count, and "RDW"; HEM-03, Monocytes; HEM-04, Lymphocytes and Monocytes. The review is not signed by the laboratory director. The corrective action taken states, "Call Abbott Lab for maintenance on Cell-Dyn machine. Quality control performed each morning on Cell-Dyn." The corrective action documented fails to evaluate the probable cause of the unacceptable results. 5. API 2018 3rd event, unacceptable result for sample HEM-15, Monocytes. No review or corrective action documented. Review of 2017, 2018 and 2019 laboratory "API SIGN OFF SHEET" records, used by the laboratory to document the laboratory director had completed his review of the API PT results, revealed the laboratory director had signed his reviews before the API PT results had been received by the laboratory. For example: At time of survey, 3/21/19, the API PT results for the 1st event of 2019 had not been received by the laboratory. The laboratory director signed his review of this PT event on 3/18 /19. Interview with TP #1 at approximately 1:30 p.m. confirmed the "API SIGN OFF SHEET" was used by the laboratory to document the laboratory director had completed his review of the API PT results. TP #1 also confirmed that the laboratory

	had not received the results for the 1st API PT event of 2019. This deficiency was previously cited in 2014 and 2017.